

510(k) Summary**Manufacturer and Submitter**

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Date Summary Prepared: September 27, 2010

OCT 1 2010

Device

Trade/Device Name: Spectralis™ HRA+OCT
Common/Usual Name: Retina Angiograph / Optical Coherence Tomograph
Classification Name: Ophthalmoscope, AC-powered
Regulation Number: 21 CFR 886.1570
Product Code: MYC, OBO
Classification Panel: Ophthalmic
Classification: Class II

Device Description

The Spectralis HRA+OCT is a real-time imaging system of the posterior segment of the human eye and for aiding in the assessment and management of various diseases of the posterior segment, such as age-related macular degeneration, diabetic retinopathy, and glaucoma. The device is a combination of optical coherence tomography (OCT) with confocal scanning laser ophthalmoscopy (cSLO). OCT imaging includes high-resolution cross-sectional imaging of ocular structures (e.g., retina, macula, optic nerve head); cSLO imaging includes high-resolution and dynamic infrared reflectance, blue reflectance, fluorescein angiography, indocyanine green angiography, and autofluorescence imaging. OCT images and cSLO images are acquired simultaneously and are viewed side-by-side on the computer screen. Images are acquired and stored using Spectralis operation software, which runs on a standard personal computer. Spectralis components include a laser scanning camera, camera mount with headrest, operation panel, power supply box, operation software, and host computer.

Intended Use/Indications for Use

The Spectralis HRA+OCT is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging, fundus photography, and fluorescence imaging (fluorescein, indocyanine green and autofluorescence), and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases including: age-related macular degeneration, macular edema, diabetic retinopathy, retinal and choroidal vascular diseases, glaucoma, and for viewing geographic atrophy as well as changes in the eye that result from neurodegenerative diseases. The Spectralis HRA+OCT includes a retinal nerve fiber layer thickness normative database, which is used to quantitatively compare the retinal nerve fiber layer in the human retina to a database of Caucasian normal subjects; the classification result is valid only for Caucasian subjects.

Substantial Equivalence Analysis

The Spectralis HRA+OCT has the same intended use and basic technological characteristics as the Heidelberg HRA2/OCT (K063191). The device has been updated to include new optical layout and components, new electronic components, new mechanical design, and new software including the addition of a normative database for RNFL thickness. These differences do not adversely affect safety or effectiveness, as verified with clinical and bench testing. Predicate devices incorporating similar technology features to the upgraded Spectralis device include: the STATUS OCT with Retinal Nerve Fiber Layer Normative Database (K030433) for the similarity in having a normative database, and the IRI Integrated Retinal Imager (K062295) for the autofluorescence intended use.

Performance - Bench Testing

The Spectralis HRA+OCT has been tested according to IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-4 and was found to meet all requirements. The system is a laser product of Class 1 according to 21 CFR §1040.10 and complies with IEC 60825-1.

Accuracy testing was performed to determine the accuracy of measurements in the OCT images, as well as in the reflectance and angiography images. Results of this study confirmed accuracy of measured values compared to one another and compared to the true value, verifying that the performance of the Spectralis device is accurate and within stated specifications.

Performance - Clinical Evaluation

Reproducibility and Repeatability

A study in human volunteers was conducted to ensure Repeatability and Reproducibility of Spectralis HRA+OCT device measurements. All possible measures were evaluated for the Spectralis HRA+OCT. For reproducibility and repeatability, the coefficients of variation of the measured endpoints were within the specified range for this device.

Normative Database

The normative database includes 201 subjects of Caucasian origin enrolled in a patient registry. Demographically, the subjects included: 111 male, 90 female, mean (SD) age 48.2 ± 14.5 years, age range 18 to 78 years. Included subjects had no history of glaucoma, normal intraocular pressure, normal visual field, normal appearance of optic disc, etc. Screening for entry into the study included patient history and physical examination to determine if eyes were "normal" by two ophthalmologists.

If subjects had a normal examination and no medical history of ocular pathology, images were acquired and measurements were then made using the Spectralis HRA+OCT device per Instructions for Use to measure RNFL thickness. Results were compiled to form a normative database of RNFL thickness. The database is limited by a sample size of 201 subjects (1 case in the <20 years age group, 13 cases in the >70 years age group), Caucasian ethnicity, and inclusion of subjects with refractive errors in the range from +5 diopters to -7 diopters.

Normative database limitations described above should be considered when examining subjects whose characteristics differ from those included in the database.

RNFL thickness measurements made with the Spectralis HRA +OCT are compared to the normative database. For that purpose, an age-adjustment of the normal database is performed and percentile limits of the normal distribution are computed as follows.

For each subject in the normative database, RNFL thickness at each point along the circle scan, mean RNFL thickness along the whole circle scan (global), and mean RNFL thickness within certain sectors of the circle scan (temporal, temporal-superior, temporal-inferior, nasal, nasal-superior, nasal-inferior) were measured. From these measurements, the age-adjusted percentiles of the database sample of 201 healthy Caucasians were determined. These age-adjusted percentiles form the basis for highlighting a result as being within or outside the normal limits (greater than the 5th or less than the 1st percentile of the database sample). The meaning of the nth percentile is that n percent of normal Caucasian subjects from the database sample have a RNFL thickness of less than or equal to this value.

Age-adjustment of the normal data is based on the linear regression of RNFL thickness vs. age of the normal subjects. Global RNFL thickness and RNFL thickness in the sectors temporal, temporal-superior, temporal-inferior, and nasal-inferior showed negative slopes (decrease of RNFL thickness) with age in the normal data and are adjusted. RNFL thicknesses in the sectors nasal and nasal-superior showed insignificant positive slopes with age in the normal data and are not adjusted.

As an example for the effect of age, the following tables show the values of the 1st and 5th percentile of RNFL thickness global and in the six sectors for ages 45 and 65 years. All values are in microns; the numbers in brackets represent the 95% confidence intervals of the respective percentiles.

Age 45 years

	1 st percentile (95% CI)	5 th percentile (95% CI)
Global	76.0 (73.2 - 78.2)	82.1 (79.9 - 83.9)
sector T	46.9 (42.8 - 49.5)	54.9 (51.7 - 57.0)
sector TS	96.3 (90.8 - 100.0)	107.4 (103.1 - 110.4)
sector TI	99.1 (92.7 - 103.1)	111.6 (106.6 - 115.0)
sector N	38.3 (34.0 - 42.0)	48.1 (44.6 - 51.0)
sector NS	57.8 (52.0 - 62.6)	70.7 (66.1 - 74.6)
sector NI	53.6 (46.7 - 59.2)	68.8 (63.4 - 73.3)

Age 65 years

	1 st percentile (95% CI)	5 th percentile (95% CI)
Global	74.5 (71.7 - 76.7)	80.6 (78.4 - 82.4)
sector T	43.9 (39.8 - 46.5)	52.0 (48.8 - 54.1)
sector TS	93.0 (87.6 - 96.8)	104.1 (99.8 - 107.2)
sector TI	94.6 (88.2 - 98.6)	107.1 (102.1 - 110.4)
sector N	38.3 (34.0 - 42.0)	48.1 (44.6 - 51.0)
sector NS	57.8 (52.0 - 62.6)	70.7 (66.1 - 74.6)
sector NI	51.9 (45.0 - 57.5)	67.2 (61.7 - 71.7)

Agreement Study with Predicate

An agreement study was conducted to compare RNFL classification results from Spectralis HRA+OCT to results from Stratus in normal and glaucoma eyes. Healthy subjects (n=101) and glaucoma patients (n=183) were examined using Spectralis and Stratus. Results of this analysis indicate that there is a good linear correlation between RNFL thickness measurements with the Spectralis and Stratus devices for healthy and for glaucoma subjects and in all measurement regions. The slopes and intercepts of the regression lines are in the neighborhood of 1 and 0, respectively, although they vary in the different measurement regions. Because of these differences, Spectralis and Stratus RNFL thickness measurement results should not be used interchangeably. (This is in agreement with the published literature.)

Studies in Eyes with Disease

Case Reports and Case Series of eyes from patients with various pathologies were examined with Spectralis HRA+OCT and these images show that no artifacts were found and there were no unexpected RNFL thickness measurement results or unexpected classification results. RNFL thickness was found to be predictably decreased in glaucoma subjects.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
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Heidelberg Engineering GmbH
c/o Diane Mandell-Horwitz, Ph.D., RAC
Official Correspondent and Consultant
The Weinberg Group, Inc.
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OCT 01 2010

Re: K101223
Trade/Device Name: Spectralis™ HRA + OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope, AC-Powered
Regulatory Class: II
Product Code: OBO, MYC
Dated: September 29, 2010
Received: September 29, 2010

Dear Dr. Mandell-Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

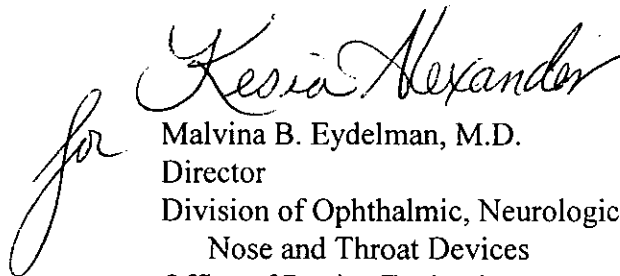
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

for *Malvina B. Eydelman*

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K101223**

Device Name: **Spectralis™ HRA+OCT**

Indications For Use:

The Spectralis HRA+OCT is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging, fundus photography, and fluorescence imaging (fluorescein, indocyanine green and autofluorescence), and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases including: age-related macular degeneration, macular edema, diabetic retinopathy, retinal and choroidal vascular diseases, glaucoma, and for viewing geographic atrophy as well as changes in the eye that result from neurodegenerative diseases. The Spectralis HRA+OCT includes a retinal nerve fiber layer thickness normative database, which is used to quantitatively compare the retinal nerve fiber layer in the human retina to a database of Caucasian normal subjects; the classification result is valid only for Caucasian subjects.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David L. Kaufman, M.D.
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K101223